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| APPLICATION NO.  | FILING DATE           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------|----------------------|---------------------|------------------|
| 09/800,448   | 03/05/2001            | Santu Bandyopadhyay  | A34065              | 2808             |
| 21003 7590 04/12/2007<br>BAKER BOTTS L.L.P.<br>30 ROCKEFELLER PLAZA<br>44TH FLOOR<br>NEW YORK, NY 10112-4498 |                       |                      | EXAMINER            |                  |
|  |                       |                      | EWOLDT, GERALD R    |                  |
|  |                       |                      | ART UNIT            | PAPER NUMBER     |
|  |                       |                      | 1644                |                  |
|  |                       |                      |                     |                  |
| SHORTENED STATUTOR   | RY PERIOD OF RESPONSE | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS   |                       | 04/12/2007           | PAPER               |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  |  | $\mathcal{L}$   |  |  |
|--|--|---|--|--|
|  | Application No.  | Applicant(s)  |  |  |
|  | 09/800,448   | BANDYOPADHYAY ET AL.  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |
|  | G. R. Ewoldt, Ph.D.  | 1644  |  |  |
| The MAILING DATE of this communication Period for Reply  | appears on the cover sheet with  | h the correspondence address  |  |  |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory per  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b). | C DATE OF THIS COMMUNIC<br>R 1.136(a). In no event, however, may a re-<br>riod will apply and will expire SIX (6) MONT<br>atute, cause the application to become ABA | ATION. ply be timely filed  THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). |  |  |
| Status   |  |   |  |  |
| 1) Responsive to communication(s) filed on 2   | 2 February 2007.   |   |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ 1  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |   |  |  |
| 3) Since this application is in condition for allo   | · · · · · · · · · · · · · · · · · · ·  |   |  |  |
| closed in accordance with the practice unde  | er <i>Ex parte Quayle</i> , 1935 C.D.  | 11, 453 O.G. 213.   |  |  |
| Disposition of Claims  |  |   |  |  |
| 4)⊠ Claim(s) <u>39-64</u> is/are pending in the applica  | ation.   |   |  |  |
| 4a) Of the above claim(s) is/are without   | drawn from consideration.  |   |  |  |
| 5) Claim(s) is/are allowed.  |  |   |  |  |
| 6)⊠ Claim(s) <u>39-64</u> is/are rejected.   |  |   |  |  |
| 7) Claim(s) is/are objected to.  | . •  |   |  |  |
| 8) Claim(s) are subject to restriction an  | d/or election requirement.   |   |  |  |
| Application Papers   |  |   |  |  |
| 9)☐ The specification is objected to by the Exam   | niner.   |   |  |  |
| 10) The drawing(s) filed on is/are: a) =   | accepted or b)⊡ objected to b  | y the Examiner.   |  |  |
| Applicant may not request that any objection to  | the drawing(s) be held in abeyand  | ce. See 37 CFR 1.85(a).   |  |  |
| Replacement drawing sheet(s) including the cor   |  |   |  |  |
| 11)☐ The oath or declaration is objected to by the   | Examiner. Note the attached  | Office Action or form PTO-152.  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |
| 12) ☐ Acknowledgment is made of a claim for fore   | eign priority under 35 U.S.C. §  | 119(a)-(d) or (f).  |  |  |
| a) All b) Some * c) None of:   |  |   |  |  |
| 1. Certified copies of the priority docum  | ents have been received.   |   |  |  |
| 2. Certified copies of the priority docum  | ents have been received in Ap  | oplication No   |  |  |
| <ol><li>Copies of the certified copies of the p</li></ol>  | priority documents have been   | received in this National Stage   |  |  |
| application from the International Bu  | reau (PCT Rule 17.2(a)).   |   |  |  |
| * See the attached detailed Office action for a  | list of the certified copies not r   | eceived.  |  |  |
|  | •  |   |  |  |
|  |  |   |  |  |
| Attachment(s)  | ·  | (070,440)   |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>   |  | ummary (PTO-413)<br>)/Mail Date   |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)   | 5) Notice of In  | formal Patent Application   |  |  |
| Paper No(s)/Mail Date  | 6)   | <del>_</del>  |  |  |

Application/Control Number: 09/800,448

Art Unit: 1644

## DETAILED ACTION

Page 2

- 1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 2/22/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment remarks have been entered.
- Claims 1-38 have been canceled.
   New Claims 39-64 are pending.
- 3. Upon reconsideration, and in view of the cancellation of all previously pending claims and the submission of new claims, all previous rejections have been withdrawn.
- 4. The following are new grounds for rejection.
- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39-64 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) An *in vitro* method for producing mature dendritic Langerhans cells, said method comprising:
- a. culturing peripheral blood monocytes in a medium containing mammalian platelets;
- b. incubating the culture at about 30°C to about 40°C for a period sufficient to enable formation of mature dendritic

Art Unit: 1644

Langerhans cells; and

c. analyzing the cultured cells for the appearance of dendritic processes and markers associated with dendritic Langerhans cells,

Page 3

wherein the presence of dendritic morphology and processes and reactivity to anti-CD 1a, anti-CD80, and anti-CD83 monoclonal antibodies indicates growth of mature dendritic Langerhans cells (Claim 39).

- B) The method of claim 39 (or 52) further comprising analyzing the mature dendritic Langerhans cells produced by flow cytometry. (Claims 48 and 61).
- C) The method of claim 39 wherein the platelets are from rat and peripheral blood monocytes are from mouse (Claim 41).
- D) An *in vitro* method for producing mature dendritic Langerhans cells, said method comprising:
- a. culturing a preparation of bone marrow cells in a medium containing mammalian platelets;
- b. incubating the culture at about 30°C to about 40°C for a period sufficient to enable formation of mature dendritic Langerhans cells; and
- c. analyzing the cultured cells for the appearance of dendritic processes and markers associated with dendritic Langerhans cells,

wherein a subpopulation of the culture differentiates into dendritic Langerhans cells, and wherein the presence of dendritic morphology and processes and reactivity to anti-CD 1a, anti-CD80, and anti-CD83 monoclonal antibodies indicates growth of mature dendritic Langerhans cells (Claim 52).

Applicant cites no specific support for any of the new claims and none has bee found.

Regarding A), the specification does not disclose (a) the culturing of any monocyte with any mammalian platelet. Nor does the specification support (b) a temperature range of "about" 30°C to "about" 40°C. Nor does the specification support the generic "analyzing" step of (c). Neither does the specification support the final "wherein" clause.

Regarding B), the specification does not disclose the generic flow cytometry analysis of the claimed method.

Art Unit: 1644

Regarding C), the specification does not disclose the culture of rat platelets with mouse blood monocytes.

Regarding D), the specification does not disclose (a) the culturing of any bone marrow cell with any mammalian platelet. Nor does the specification support (b) a temperature range of "about" 30°C to "about" 40°C. Nor does the specification support the generic "analyzing" step of (c). Neither does the specification support the final "wherein" clause.

- 7. No claim is allowed.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.
- 9. Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://www.pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

G.R. Ewoldt, Ph.D.

Primary Examiner

Technology Center 1600